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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUCAMPO AG, SUCAMPO PHARMACEUTICALS, INC., SUCAMPO PHARMA, LLC, TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC., and TAKEDA PHARMACEUTICALS AMERICA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., and Sucampo Pharma, LLC (collectively, "Sucampo") and Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") (together with Sucampo, "Plaintiffs"), for their Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sucampo AG is a Swiss corporation having a primary place of business at Baarerstrasse 22, CH-6300, Zug, Switzerland.

2. Plaintiff Sucampo Pharmaceuticals, Inc. is a corporation having a principal place of business at 805 King Farm Boulevard, Suite 550, Rockville, Maryland 20850, USA.

3. Plaintiff Sucampo Pharma, LLC, which merged with a Japanese corporation previously known as R-Tech Ueno, Ltd., is a wholly-owned subsidiary of Sucampo Pharmaceuticals, Inc., having a principal place of business at 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan.

4. Plaintiff Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

5. Plaintiff Takeda Pharmaceuticals USA, Inc. is a corporation jointly owned by Takeda Pharmaceutical Company Limited and non-party Takeda Pharmaceuticals International AG, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

7. Upon information and belief, Defendant Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard., Third Floor, Bridgewater, New Jersey 08807.

8. Upon information and belief, Amneal is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600211542.

9. Upon information and belief, Amneal is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5002991.

10. Upon information and belief, Amneal has appointed the Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628, as its registered agent for service of process in New Jersey.

11. Upon information and belief, Amneal has at least five places of business in New Jersey, including, but not limited to, the following business addresses: (1) U.S. Corporate Headquarters, 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807; (2) Liquids Manufacturing, 131 Chambersbrook Road, Branchburg, New Jersey 08876; (3) Primary Packaging Facility, 1 Murray Road, East Hanover, New Jersey 07936; (4) Oral Solids Manufacturing, 209 McLean Boulevard, Paterson, New Jersey 07504; and (5) Transdermal, Topicals & Complex Oral Solids Manufacturing and R&D, 1 New England Avenue, Piscataway, New Jersey 08854.

12. Upon information and belief, Amneal develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District.

13. Upon information and belief, Amneal markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

14. This is a civil action for infringement of United States Patent Nos. 6,982,283, 8,097,653, 8,389,542, 8,026,393, 8,338,639 (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

17. This Court has personal jurisdiction over Amneal because, *inter alia*, (1) Amneal has its principal place of business in the State of New Jersey; (2) Amneal has at least five places of business in the State of New Jersey; (3) Amneal develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; and (4) Amneal has affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution, or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey.

18. This Court also has personal jurisdiction over Amneal because, *inter alia*, Amneal has committed, or aided, abetted, contributed to, or participated in the commission of,

acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

19. Amneal also sent Sucampo a Notice Letter dated March 1, 2017, stating that Amneal filed Abbreviated New Drug Application ("ANDA") No. 209450 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market, or sell generic lubiprostone capsules 8 mcg and 24 mcg in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the patents-in-suit.

20. This Court also has personal jurisdiction over Amneal because, *inter alia*, Amneal has availed itself of the legal protections of the State of New Jersey and consented to personal jurisdiction in this Judicial District. *See, e.g.*, *Sumitomo Dainippon Pharma Co., Ltd., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 16-4596 (SRC)(CLW) (D.N.J. July 29, 2016); *Genzyme Corporation, et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 16-3892 (SRC)(CLW) (D.N.J. June 29, 2016); *Horizon Pharma Ireland Ltd., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 16-00646 (NLH)(AMD) (D.N.J. Feb. 5, 2016); *Symed Labs Limited, et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-8307 (CCC)(MF) (D.N.J. Nov. 25, 2015); *BTG International Limited, et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 15-5909 (KM)(JBC) (D.N.J. July 31, 2015); *Warner Chilcott Company, LLC v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-3590 (MLC)(DEA) (D.N.J. May 28, 2015); *Shire Development LLC, et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 15-2865 (RBK)(JS) (D.N.J. Apr. 22, 2015); *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 15-1585 (JBS)(KMW) (D.N.J. Mar. 2, 2015).

THE PATENTS-IN-SUIT

21. Plaintiff Sucampo Pharmaceuticals, Inc. holds approved New Drug Application ("NDA") No. 021908, under which the FDA granted approval on January 31, 2006 for 24 mcg lubiprostone capsules and on April 29, 2008 for 8 mcg lubiprostone capsules, both marketed in the United States under the trade name AMITIZA®.

22. AMITIZA® (lubiprostone) capsules approved in NDA No. 021908 are indicated for the treatment of chronic idiopathic constipation in adults and the treatment of opioid-induced constipation in adults with chronic, non-cancer pain. In addition, AMITIZA® (lubiprostone) capsules are indicated for the treatment of irritable bowel syndrome with constipation ("IBS-C") in women ≥ 18 years old.

23. Sucampo AG owns United States Patent No. 6,982,283 ("the '283 patent") titled "Method For Treating Drug-Induced Constipation." The '283 patent was duly and legally issued on January 3, 2006. A copy of the '283 patent is attached as Exhibit A.

24. Sucampo AG owns United States Patent No. 8,097,653 ("the '653 patent") titled "Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation." The '653 patent was duly and legally issued on January 17, 2012. A copy of the '653 patent is attached as Exhibit B.

25. Sucampo AG owns United States Patent No. 8,389,542 ("the '542 patent") titled "Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation." The '542 patent was duly and legally issued on March 5, 2013. A copy of the '542 patent is attached as Exhibit C.

26. Sucampo AG and Sucampo Pharma, LLC co-own United States Patent No. 8,026,393 ("the '393 patent") titled "Soft-Gelatin Capsule Formulation." The '393 patent was duly and legally issued on September 27, 2011. A copy of the '393 patent is attached as Exhibit D.

27. Sucampo AG and Sucampo Pharma, LLC co-own United States Patent No. 8,338,639 ("the '639 patent") titled "Soft-Gelatin Capsule Formulation." The '639 patent was duly and legally issued on December 25, 2012. A copy of the '639 patent is attached as Exhibit E.

28. Takeda Pharmaceutical Company Limited is an exclusive licensee to the patents-in-suit. Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceutical Company Limited. Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc.

29. The patents-in-suit are listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for AMITIZA®.

AMNEAL ANDA NO. 209450 AND NOTICE LETTER

30. Upon information and belief, Amneal submitted ANDA No. 209450 to the FDA, including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of generic lubiprostone oral capsules, 8 mcg and 24 mcg (collectively, "ANDA Products") prior to expiration of the patents-in-suit.

31. Upon information and belief, on or about March 1, 2017, Amneal sent a Paragraph IV Certification Notice Letter to Sucampo. In its Notice Letter, Amneal represented

that ANDA No. 209450 contained Paragraph IV Certifications with respect to the '283, '393, '639, '653, and '542 patents, and that Amneal sought approval of ANDA No. 209450 prior to the expiration of those patents. On or about March 2, 2017, Sucampo first received Amneal's Paragraph IV Certification Notice Letter.

32. Plaintiffs commenced this action within 45 days of the date of receipt of the Amneal Paragraph IV Certification Notice Letter dated March 1, 2017.

INFRINGEMENT OF THE PATENTS-IN-SUIT

33. Plaintiffs repeat and re-allege paragraphs 1-33 as if fully set forth herein.

34. By seeking approval of ANDA No. 209450 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '283, '653, '542, '393, and '639 patents, Amneal has infringed one or more claims of those patents under 35 U.S.C. § 271(e)(2)(A).

35. If Amneal manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the ANDA Products prior to the expiration of the '283, '653, '542, '393, and '639 patents, Amneal will infringe one or more claims of those patents under 35 U.S.C. § 271(a), (b), or (c).

36. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Amneal's ANDA be a date that is not earlier than the expiration date of the '283, '653, '542, '393, and '639 patents, or any later expiration of any patent term extension or exclusivity for these patents to which Plaintiffs are or become entitled.

37. Plaintiffs are entitled to a declaration that, if Amneal commercially manufactures, uses, offers for sale, or sells the ANDA Products within the United States, imports the ANDA Products into the United States, or induces or contributes to such conduct, Amneal will infringe the '283, '653, '542, '393, and '639 patents under 35 U.S.C. § 271(a), (b), or (c).

38. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Amneal has infringed the '283, '653, '542, '393, and '639 patents by submitting ANDA No. 209450 to the FDA;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Amneal, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Amneal, from infringing the '283, '653, '542, '393, and '639 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the aforementioned patents;

C. An Order pursuant to 35 U.S.C, § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 209450 be a date that is not earlier than the expiration date of the '283, '653, '542, '393, and '639 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Amneal commercially manufactures, uses, offers for sale, or sells within the United States, or imports

into the United States any product that infringes or induces or contributes to the infringement of the '283, '653, '542, '393, and '639 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

E. Such other and further relief as the Court may deem just and proper.

Dated: April 13, 2017

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: April 13, 2017

By: s/ Charles M. Lizza

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